RECORD AND BRIEFS

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Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC., PETITIONER

v.

AMGEN INC., ET AL.

AMGEN INC., ET AL.,
CONDITIONAL CROSS-PETITIONERS

v.

SANDOZ INC.

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER/CROSS-RESPONDENT

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 804, establishes an abbreviated process for licensing "biosimilar" versions of licensed biological products (reference products). 42 U.S.C. 262(k). In conjunction with that process, the BPCIA establishes a series of steps for the resolution of potential patent claims by the sponsor of the reference product and the biosimilar applicant. § 262(*l*). Among other things, Subsection (*l*)(2)(A) of Section 262 provides that the applicant "shall provide to" the sponsor a copy of the biosimilar application and information about the product's manufacturing processes. Subsection (*l*)(8)(A) provides that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

1. The question presented in No. 15-1195 is whether Subsection (*l*)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an immediate action for patent infringement.

2. The questions presented in No. 15-1039 are (a) whether notice of commercial marketing under Subsection (*l*)(8)(A) is legally effective if it is given before Food and Drug Administration (FDA) approval of the biosimilar application, and, if not, (b) whether Subsection (*l*)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER/CROSS-RESPONDENT

INTEREST OF THE UNITED STATES

Section 351 of the Public Health Service Act, 42 U.S.C. 262 (hereinafter Section 262), governs licensing of biological products and establishes a process for contemporaneously resolving certain related patent disputes. The Food and Drug Administration (FDA) administers that licensing process and implements related provisions. *E.g.*, 42 U.S.C. 262(a) and (k). The United States Patent and Trademark Office is responsible for issuing patents and, through the Secretary of

Commerce, advising the President on patent policy. 35 U.S.C. 2(a)(1) and (b)(8). At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. This case concerns the framework in 42 U.S.C. 262(*l*) for facilitating the resolution of certain patent disputes that arise in connection with FDA licensing of "biological products" (also known as "biologics") under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 804.[1]

A "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein * * * , or analogous product * * * applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. 262(i)(1). Biologics may be "isolated from a variety of natural sources—human, animal, or microorganism"—and generally are more complex than drugs approved under 21 U.S.C. 355.[2]

a. Section 262 establishes two routes for biologic licensing. 42 U.S.C. 262(a)(1)(A). First, FDA may license a biologic under Section 262(a) if, *inter alia*, the biologic itself has been demonstrated to be "safe, pure, and potent." § 262(a)(2)(C)(i). Second, the BPCIA provides, in Section 262(k), an abbreviated licensing process generally analogous to the process for approv-

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[1] The BPCIA's primary provisions are codified at 28 U.S.C. 2201(b), 35 U.S.C. 271(e)(2)(C), (4)(B)-(D), and (6), and 42 U.S.C. 262(i) and (k)-(m).

[2] FDA, *What Are "Biologics" Questions and Answers* (2015), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

ing generic drugs under the Hatch-Waxman Amendments, 21 U.S.C. 355(j). Under Section 262(k), FDA may approve an abbreviated biologic license application (aBLA) if, *inter alia*, the biologic at issue is shown to be "biosimilar" to a previously approved biologic (*i.e.*, the "reference product"). 42 U.S.C. 262(k)(3)(A); see § 262(i)(2) and (4). Developing a biosimilar is substantially more time-consuming and expensive than developing a generic drug, with estimates ranging from approximately eight to ten years and $100-$200 million for development.[3] In addition, establishing commercial manufacturing facilities for biological products can cost $250 million to $1 billion.[4]

An applicant seeking a license for a biologic may pursue either of the two routes above. But if it elects to submit an aBLA, the BPCIA prohibits its submission earlier than four years after FDA first licensed the reference product and prohibits FDA from making its approval effective earlier than 12 years after that first licensing of the reference product. 42 U.S.C. 262(k)(7)(A) and (B).

b. A reference product may be protected by various patents, including product (*e.g.*, composition) patents, method-of-use patents, and manufacturing-process patents. But without the BPCIA's special patent-dispute-resolution provisions, patent litigation, including issues of patent invalidity, would have faced obstacles if filed *before* a biosimilar is licensed and

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[3] Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* 14 (June 2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[4] *Ibid.*

marketed, for two primary reasons. First, it is not an act of patent infringement "to make, use, offer to sell, or sell * * * a patented invention" (other than a new animal drug or veterinary biological product) "solely for uses reasonably related to the development and submission of information," 35 U.S.C. 271(e)(1), while seeking approval for, *inter alia*, a "human biological product[]." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 665, 674 (1990); see *id.* at 668-669. Second, anticipatory infringement claims would have had to overcome ripeness concerns if litigated before FDA approval and actual commercial marketing of a biosimilar. Cf. § 271(a) (infringement includes "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention").

i. The BPCIA facilitates early resolution of patent claims by establishing a so-called "artificial" patent-infringement claim that may be litigated while FDA reviews an aBLA. Cf. *Eli Lilly & Co.*, 496 U.S. at 675-678 (discussing "artificial" infringement in generic-drug context). A generally applicable Patent Act provision provides private parties with a "civil action for [patent] infringement." 35 U.S.C. 281. In two specific situations discussed below, the BPCIA makes it "an act of infringement [with respect to specified categories of patents] to submit" an "application seeking approval of a biological product" if the "purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a * * * biological product claimed in a patent or the use of which is claimed in a patent" before that patent expires. § 271(e)(2)(C).

ii. Section 262(*l*), in turn, establishes a four-phase process for resolving patent disputes in litigation be-

tween the aBLA applicant (applicant) and the reference-product sponsor (sponsor). See 42 U.S.C. 262(*l*)(2)-(9). This brief refers to those phases as the

(1) Information Phase, § 262(*l*)(2);
(2) Comprehensive List Phase, § 262(*l*)(3);
(3) Round 1 Litigation Phase, § 262(*l*)(4)-(6); and
(4) Round 2 Litigation Phase, § 262(*l*)(8) and (9)(A).

The BPCIA further provides detailed consequences for failing to follow Section 262(*l*)'s patent-dispute-resolution process. See 35 U.S.C. 271(e)(2)(C) and (6); 42 U.S.C. 262(*l*)(9)(B) and (C). Those consequences, as explained below, can accelerate the timing, and modify the scope, of the ensuing patent litigation.

First, in the Information Phase, the applicant "shall provide to the * * * sponsor," within 20 days of FDA's acceptance of its aBLA for review, both a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The sponsor's "confidential access" to that "information required to be produced pursuant to [Section 262(*l*)](2)" is for the "sole and exclusive purpose" of allowing the sponsor to determine "whether a claim of patent infringement could reasonably be asserted if the [applicant] engaged in the manufacture, use, offering for sale, sale, or importation" of its biosimilar. § 262(*l*)(1)(B)(i) and (D); see § 262(*l*)(1)(H) (authorizing "immediate injunctive relief" for improper disclosure).

If the applicant, however, "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA is deemed an (artificial) "act of infringement" with respect to "a patent that could be identified pursuant to [S]ection [262](*l*)(3)(A)(i)" by the sponsor in the Comprehensive List Phase, discussed below. 35 U.S.C.

271(e)(2)(C)(ii). The sponsor may then file a patent-infringement action under the private right of action in 35 U.S.C. 281. Also, due to the applicant's "fail[ure] to provide" the "information required under [Section 262(*l*)](2)(A)," the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The question presented in No. 15-1195 concerns whether, in addition to those express statutory consequences, a court may enjoin the applicant to provide the Section 262(*l*)(2)(A) information to the sponsor.

Second, in the Comprehensive List Phase, the sponsor and applicant produce a list of patents on which (actual) patent-infringement claims could reasonably be asserted "if a person * * * engaged in the making, using, offering to sell, selling, or importing" of the biosimilar, 42 U.S.C. 262(*l*)(3)(A)(i) and (B)(i). See § 262(*l*)(3). Within 60 days of receiving the applicant's aBLA and manufacturing-process information, the sponsor "shall provide" to the applicant a list of such patents, § 262(*l*)(3)(A)(i), and identify which patents, if any, it would be prepared to license, § 262(*l*)(3)(A)(ii). If the sponsor fails timely to include "a patent that should have been included in the list," the sponsor cannot later assert any claim for "infringement of the patent with respect to the [applicant's biosimilar]." 35 U.S.C. 271(e)(6)(C).

Within 60 days after receipt of the sponsor's list, the applicant "may provide" the sponsor with its own list of patents on which "infringement [claims] could reasonably be asserted"; "shall provide" a response to each patent on the sponsor's list explaining why commercially marketing the biosimilar will not violate the

sponsor's patent rights; and "shall provide" a response to the sponsor's licensing offer. 42 U.S.C. 262(*l*)(3)(B). Within 60 days after receipt of the applicant's list, the sponsor then "shall provide" the applicant a detailed statement why the patents on the sponsor's list would be infringed and a response concerning the validity and enforceability of patents on the applicant's list. § 262(*l*)(3)(C).

The applicant's submission of its aBLA is deemed an (artificial) act of infringement "with respect to a patent that is identified in the list of patents described in [S]ection [262](*l*)(3)," *i.e.*, in the Comprehensive List. 35 U.S.C. 271(e)(2)(C)(i). As discussed below, however, other BPCIA provisions control the timing and scope of infringement claims for patents identified on the Comprehensive List, which can proceed in two potentially overlapping rounds of litigation.

Third, in the Round 1 Litigation Phase, the applicant and sponsor identify patents for prompt (Round 1) infringement litigation. 42 U.S.C. 262(*l*)(4)-(6). If within 15 days they reach agreement on such a "list of * * * patents," the "sponsor shall bring an action for patent infringement with respect to each such patent" within 30 days. § 262(*l*)(4) and (6)(A).

If they do not reach agreement within 15 days, the applicant "shall notify" the sponsor of "the number of patents" that the applicant will designate for its Round 1 list; then within five days, the applicant and sponsor "shall simultaneously" exchange their Round 1 lists. 42 U.S.C. 262(*l*)(5)(A) and (B)(i). The "number of patents listed" by the sponsor for Round 1 litigation may not exceed the number listed by the applicant, but if the applicant lists no patents the sponsor may list one. § 262(*l*)(5)(B)(ii). The sponsor then "shall

bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. § 262(*l*)(6)(B).

If the applicant and sponsor successfully complete the actions required of them in the Information, Comprehensive List, and Round 1 Litigation Phases, the sponsor's Round 1 artificial-infringement action will be filed no more than roughly 250 days after FDA accepts the applicant's aBLA for review. See 42 U.S.C. 262(*l*)(2)-(6). But if the sponsor fails to file the Round 1 litigation within the requisite 30-day period, or if its action for infringement of a patent on a Round 1 list is dismissed without prejudice or not prosecuted in good faith, the sponsor's "sole and exclusive" remedy for infringement of such a Round 1 patent is a "reasonable royalty." 35 U.S.C. 271(e)(6)(A) and (B).

Fourth, the Round 2 Litigation Phase covers the remaining patents on the Comprehensive List not included on the Round 1 list. Cf. 42 U.S.C. 262(*l*)(8)(B)(i) and (ii) (remaining patents). The BPCIA normally postpones litigation on the Round 2 patents. Specifically, if the applicant timely provided the sponsor with the information required in Subsection (*l*)(2)'s Information Phase, neither the sponsor nor the applicant may bring a declaratory-judgment action based on a Round 2 patent before the applicant provides advance notice of the first commercial marketing of its biosimilar. § 262(*l*)(9)(A).

Section 262(*l*)(8)(A) governs the timing of that notice. It provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42 U.S.C. 262(*l*)(8)(A). The questions presented in No. 15-1039 concern whether that notice may be given

before FDA approval of the biosimilar and, if not, whether a court may enjoin the applicant's marketing of its biosimilar for 180 days after FDA approval.

When such notice is given, the bar preventing the sponsor and applicant from bringing a declaratory-judgment action concerning the infringement, validity, or enforcement of a Round 2 patent is lifted. 42 U.S.C. 262(*l*)(9)(A). Moreover, "[a]fter receiving the notice * * * and before * * * the [biosimilar's] first commercial marketing," the "sponsor may seek a preliminary injunction" to enjoin the biosimilar's commercial manufacture or sale "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

Alternatively, even before any notice is given under Section 262(*l*)(8)(A), the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action concerning any patent on the sponsor's Comprehensive List (including any relevant Round 2 patent) if the applicant "fails" to complete significant steps in the Section 262(*l*) process—specifically, if the applicant fails to provide the sponsor with its timely explanation why marketing the biosimilar would not violate the sponsor's rights under patents on the sponsor's list (42 U.S.C. 262(*l*)(3)(B)(ii)); to provide the sponsor timely notice of the applicant's number of Round 1 patents or its Round 1 list (§ 262(*l*)(5)); to provide the Secretary of Health and Human Services with a timely copy of a complaint in the Round 1 litigation (§ 262(*l*)(6)(C)(i)); or to provide the sponsor the 180-day advance notice of the biosimilar's first commercial marketing (§ 262(*l*)(8)(A)). See § 262(*l*)(9)(B).

2. Since 1991, respondents/cross-petitioners (respondents) have marketed filgrastim under the brand name Neupogen. Pet. App. 8a. In May 2014, petitioner/cross-respondent (petitioner) submitted an aBLA seeking FDA approval of a biosimilar filgrastim product (with the trade name Zarxio) that listed Neupogen as its reference product. *Id.* at 8a-9a. On July 7, 2014, FDA notified petitioner that it had accepted the aBLA for review. *Id.* at 8a.

On July 8, 2014, petitioner notified respondents of the filing of petitioner's aBLA and stated petitioner's intent to launch its biosimilar immediately upon FDA approval, which it expected in "Q1/2 of 2015." Pet. App. 8a. Petitioner, however, elected not to provide respondents with a copy of its aBLA or manufacturing-process information under Section 262(*l*)(2)(A). *Ibid.* Petitioner informed respondents that respondents were therefore entitled to sue petitioner for patent infringement. *Ibid.*

3. In October 2014, respondents filed a district court action against petitioner, asserting, as relevant here, an (artificial) infringement claim based on a patent claiming a method of using filgrastim and a state-law unfair competition law (UCL) claim. Pet. App. 9a. Respondents' UCL claim rested on two alleged BPCIA violations: petitioner's failure to disclose information required by Section 262(*l*)(2)(A), and its allegedly ineffective advance notice of commercial marketing under Section 262(*l*)(8)(A). *Ibid.* Petitioner counterclaimed for a declaratory judgment on both BPCIA questions and on its contentions that respondents' patent was invalid and not infringed. *Ibid.* Respondents sought a preliminary injunction based on the state-law claims to prevent petitioner from mar-

keting its biosimilar. *Id.* at 10a, 58a. Respondents subsequently obtained petitioner's aBLA in discovery. *Id.* at 10a.

Later, on March 6, 2015, FDA approved petitioner's aBLA for all approved uses of Neupogen. Pet. App. 8a-9a. That same day, petitioner gave respondents a second notice of commercial marketing. *Ibid.*

Shortly thereafter, the district court denied injunctive relief and granted petitioner partial judgment on the pleadings. Pet. App. 56a-84a. The court concluded that petitioner permissibly declined to provide its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), *id.* at 68a-73a, and permissibly gave notice under Section 262(*l*)(8)(A) before FDA approved its aBLA, *id.* at 73a-76a. The court rejected respondents' UCL claim on those federal-law grounds. *Id.* at 77a-78a. The court subsequently entered a Rule 54(b) partial final judgment. *Id.* at 11a.

4. The Federal Circuit granted an injunction pending appeal that prohibited petitioner from marketing Zarxio, Pet. App. 31a, and subsequently affirmed in part, vacated in part, and remanded. *Id.* at 1a-55a.

a. The court of appeals first concluded that petitioner could elect not to disclose its aBLA and manufacturing information under Section 262(*l*)(2)(A), subject only to the patent-litigation consequences specified in the BPCIA. Pet. App. 12a-18a. Although Section 262(*l*)(2)(A) states that the applicant "shall" provide that information, the court concluded that the statutory text must be understood in its broader statutory context. *Id.* at 14a-15a. Other BPCIA provisions in 35 U.S.C. 271(e)(2)(C)(ii) and 42 U.S.C. 262(*l*)(9)(C), the court explained, "explicitly contemplate[]" that the applicant might not provide that in-

formation and "specifically set[] forth the consequence for such failure: the [sponsor] may bring an infringement action," and the applicant is prohibited from bringing its own declaratory-judgment "action on patents that claim the biological product or its use." Pet. App. 15a-17a. Because the BPCIA does not "specify any non-patent-based remedies" for such a failure, the court concluded that the sponsor's only recourse is to pursue its patent-infringement action, in which the sponsor can then "access the required information through discovery." *Id.* at 17a-18a. Judge Newman dissented from that holding. *Id.* at 32a-42a.

b. The court of appeals concluded, however, that an aBLA applicant must give its advance notice of first commercial marketing under Section 262(*l*)(8)(A) *after* FDA approves its aBLA. Pet. App. 18a-26a. The court reasoned that the requirement to give notice 180 days before the first commercial marketing of the applicant's "biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), contemplates that the biosimilar must be "licensed" before notice is given. Pet. App. 20a-21a. The court then "extended" its injunction enjoining the marketing of Zarxio until September 2, 2015, *i.e.*, 180 days after petitioner gave its second notice to respondents. *Id.* at 27a-28a, 31a.

Judge Chen dissented from that grant of injunctive relief. Pet. App. 42a-55a. He concluded that petitioner had no obligation to provide notice because Section 262(*l*)(8)(A) is not a "standalone provision," but rather is part of "the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)," and when, as here, the "applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 43a.

c. The court of appeals affirmed the dismissal of respondents' UCL claim alleging a Section 262(*l*)(2)(A) violation, Pet. App. 26a-27a, and deemed respondents' UCL claim based on Section 262(*l*)(8)(A) to be moot in light of the court's extension of its injunction, *id.* at 27a-28a.

SUMMARY OF ARGUMENT

I. The Federal Circuit correctly held that, where an applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), the sponsor's only recourse under the BPCIA is to bring an artificial-infringement action.

A. Section 262(*l*)(2)(A) states that the applicant "shall provide" specified information to the sponsor. That provision imposes a mandatory condition precedent for invoking Section 262(*l*)'s patent-dispute-resolution framework, but it does not address the consequences for failing to do so.

B. Congress specifically addressed those consequences in two other BPCIA provisions. First, Section 271(e)(2)(C)(ii) provides that, if an applicant fails to provide the Section 262(*l*)(2)(A) information, an artificial patent-infringement claim will arise with respect to a patent that the sponsor could have included on its Comprehensive List. 35 U.S.C. 271(e)(2)(C)(ii). The sponsor may then immediately bring suit under 35 U.S.C. 281 for patent infringement. Declaratory relief is the only relief available in such an action brought any significant amount of time before a biosimilar's commercial marketing. Second, if the applicant fails to provide the Section 262(*l*)(2)(A) information, Section 262(*l*)(9)(C) provides that the sponsor, but not the applicant, may bring an action for

declaratory relief on a product or method-of-use patent. Those express statutory consequences are exclusive.

C. Moreover, no cause of action exists for direct judicial enforcement of Section 262(*l*)(2)(A). Congress must itself create a cause of action for a litigant to enforce a federal statutory provision, yet respondents have never attempted to identify such a cause of action for their Section 262(*l*)(2)(A) claim. That omission is independently fatal to their position.

II. The Federal Circuit erred in holding that Section 262(*l*)(8)(A) requires an applicant to provide a 180-day advance notice of the first commercial marketing of its biosimilar *after* FDA licenses that biosimilar, and that a court may enjoin the applicant from such marketing until 180 days after such notice.

A. 1. Section 262(*l*)(8)(A) provides that the applicant shall provide notice to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." That text directly addresses the requisite timing by specifying the "late[st]" date "before" commercial marketing on which notice must be given. Nothing limits how early the applicant may give notice after FDA accepts its aBLA for review.

Section 262(*l*)(8)(A)'s single timing requirement reflects its function in the statutory framework. The applicant exercises substantial control over the scope of early Round 1 artificial-infringement litigation. Notice then lifts the statutory stay of artificial-infringement litigation based on the sponsor's remaining (Round 2) patents. By specifying that such notice be given at least 180 days before commercial marketing, Congress provided a reasonable period during

which the sponsor may litigate such Round 2 claims before commercial marketing. Consistent with that framework, the applicant can provide the sponsor even *more* time by giving notice earlier than necessary.

2. The Federal Circuit also erred in holding that notice is required even after the applicant declines to provide Section 262(*l*)(2)(A) information. Once the applicant has departed from Section 262(*l*)'s patent-dispute-resolution process, the sponsor may immediately bring an artificial-infringement claim for all relevant patents. As a result, the statutory function of notice—*i.e.*, to authorize litigation on Round 2 patents that the sponsor was prevented from pursuing—no longer applies.

B. In any event, injunctive relief is unavailable to enforce Section 262(*l*)(8)(A) for essentially the same reasons as it is to enforce Section 262(*l*)(2)(A): (1) The BPCIA's detailed provisions specify the exclusive consequence for failing to provide notice, *i.e.*, the sponsor may bring an artificial-infringement action for all relevant patents and, regardless, (2) no cause of action exists for judicial enforcement of the notice provision.

ARGUMENT

I. THE FEDERAL CIRCUIT CORRECTLY DENIED AN INJUNCTION TO COMPEL PETITIONER'S DISCLOSURE OF SECTION 262(*l*)(2)(A) INFORMATION

Section 262(*l*)(2)(A) provides that the applicant "shall provide" to the sponsor, within 20 days of FDA's acceptance of its aBLA, a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The BPCIA further states that "if the applicant * * * fails to provide the application and information required under [S]ection [262](*l*)(2)(A),"

the applicant's "submi[ssion]" of its aBLA constitutes an artificial "act of infringement" for certain patents, 35 U.S.C. 271(e)(2)(C)(ii), on which the sponsor may bring a "civil action for [patent] infringement," 35 U.S.C. 281. The "sponsor, but not the * * * applicant," may then seek certain declaratory relief. 42 U.S.C. 262(*l*)(9)(C). The Federal Circuit correctly held that those express patent-litigation-focused consequences are exclusive when the applicant fails to furnish information under Section 262(*l*)(2)(A). Pet. App. 12a-18a.

A. Section 262(*l*)(2)(A) Does Not Address The Consequences Of An Applicant's Failure To Satisfy The Condition It Specifies

Respondents argue (Cross-Pet. 25-27) that Section 262(*l*)(2)(A)'s use of the term "shall" in providing that the applicant "shall provide" specified information—and related statutory references to information "required" to be produced—reflect that the Federal Circuit erred in concluding that the term "shall" in this context "does not mean 'must,'" Pet. App. 15a. The government agrees that the Federal Circuit misconceived the relevant inquiry in that respect. Section 262(*l*)(2)(A) is properly understood as imposing a mandatory condition precedent for invoking Subsection (*l*)'s specialized patent-dispute-resolution framework. The mandatory nature of that condition, however, does not suggest that a sponsor may obtain a court order to compel the furnishing of the information.

The Court unanimously held this Term that, even if a statute that specifies that an action "'shall' be [taken]" "creates a mandatory rule," the mandatory language "says nothing * * * about the remedy for a violation of that rule" and thus provides no "congres-

sional guidance" about what, if any, consequence should follow. *State Farm Fire & Cas. Co.* v. *United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016). Instead, where a "statute does not specify" the "consequences" of violating a statutory procedure, this Court "look[s] to statutory language, to the relevant context, and to what they reveal about the purposes [the provision] is designed to serve." *Dolan* v. *United States*, 560 U.S. 605, 610 (2010). Here, however, the BPCIA, *does* specify the consequences for failing to provide information under Section 262(*l*)(2)(A). Those consequences are exclusive.

B. The BPCIA Elsewhere Specifies The Only Consequences For Not Providing Section 262(*l*)(2) Information

1. Two BPCIA provisions specifically address the consequences of an applicant's failure to provide the sponsor with its aBLA and manufacturing-process information "under [S]ection [262](*l*)(2)(A)." See 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C).

a. First, Section 271(e)(2)(C)(ii) provides that, when an applicant "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's "submi[ssion]" of its aBLA is an "act of infringement" if the aBLA seeks "approval * * * to engage in the commercial manufacture, use, or sale of a * * * biological product" protected by an unexpired product or method-of-use patent. 35 U.S.C. 271(e)(2)(C)(ii) ("product [is] claimed in a patent or the use of which is claimed in a patent"). That infringement extends to any "patent that could be identified pursuant to [S]ection [262](*l*)(3)(A)(i)" by the

sponsor on a Comprehensive List. *Ibid.*[5] Those detailed provisions both specify the patents for litigation and utilize Section 281's pre-existing "private right of action for patent infringement," see *POM Wonderful LLC* v. *Coca-Cola Co.*, 134 S. Ct. 2228, 2240 (2014), to allow the sponsor immediately to bring suit for patent-focused relief.

In this way, Section 271(e)(2)(C) follows the path that Congress established earlier in the generic-drug context under Section 271(e)(2)(A), which allows a patent holder to bring "a declaratory judgment action" to litigate relevant patents by "creat[ing] an 'artificial' act of infringement" to "provide[] a jurisdictional basis for a declaratory judgment suit against a generic manufacturer." *Glaxo Grp. Ltd.* v. *Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004). Such a declaratory judgment is a muscular tool: It provides a basis for both (1) prompt injunctive relief should actual infringement resulting from a later commercial launch become imminent, see 28 U.S.C. 2202 (authorizing supplemental relief "based on a declaratory judgment"), and (2) treble damages against an applicant who flouts the declaration by subsequently engaging in such (willful) infringement, cf. *Halo Elecs.*,

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[5] The infringement extends not only to product and method-of-use patents, but also to a manufacturing-process patent, when the patent could be asserted "if a person * * * engaged in the *making*, using, offering to sell, selling, or importing" of that biosimilar, 42 U.S.C. 262(*l*)(3)(A)(i) (emphasis added). That conclusion is confirmed by the fact that the applicant's provision of information on the "processes used to manufacture" its biosimilar, § 262(*l*)(2)(A), is "for the sole and exclusive purpose" of allowing the sponsor to determine if it could assert "a claim of patent infringement," § 262(*l*)(1)(D). See Pet. App. 16a n.3.

Inc. v. *Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1930, 1932-1934 (2016) (construing 35 U.S.C. 284).

b. Section 262(*l*)(9) separately imposes "[l]imitation[s] on declaratory judgment action[s]" in three subparagraphs that identify when the "sponsor" and "applicant" are prohibited from seeking declaratory relief. 42 U.S.C. 262(*l*)(9).[6] As relevant here, Section 262(*l*)(9)(C) provides that, "[i]f" the applicant "fails to provide the application and information required under [Section 262(*l*)](2)(A)," the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." § 262(*l*)(9)(C).

2. Those express statutory consequences for an applicant's failure to provide Section 262(*l*)(2)(A) information are both logical and significant. The sole function of Section 262(*l*) is to establish patent-dispute-resolution procedures that control the timing and scope of patent-infringement litigation between the sponsor and applicant. See pp. 4-9, *supra*. A central "part of the [BPCIA's] design" is that, when the applicant chooses to invoke those dispute-resolution provisions, the BPCIA gives it significant "control" over "the scope of the [Round 1] litigation," *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1062 & n.3

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[6] When an applicant brings a declaratory-judgment action as a "prospective defendant[]" to "establish [its] nonliability" on patent claims, *Beacon Theatres, Inc.* v. *Westover*, 359 U.S. 500, 504 (1959), "'federal patent law creates the cause of action'" because it reflects "the 'character of the threatened action'" that the sponsor would bring against the applicant. *Medtronic, Inc.* v. *Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014) (citations omitted).

(Fed. Cir.), cert. denied, 137 S. Ct. 591 (2016), which the sponsor must promptly initiate (about 250 days or less) after FDA accepts an aBLA. See pp. 5-8, *supra*. The applicant, for instance, may restrict that litigation to just one patent or, conversely, expand it to include all relevant patents. See 42 U.S.C. 262(*l*)(5)(B)(i)(I), (ii)(II), and (6)(B). But if the applicant declines to give timely Section 262(*l*)(2)(A) information to the sponsor, the applicant forfeits that control and the BPCIA vests the sponsor with the option of immediately bringing an (artificial) infringement action with respect to *all* relevant patents at a time of its own choosing. See pp. 17-18 & n.5, *supra*.

Where, as here, Congress has provided specific statutory consequences for failing to follow a statutory procedure, those consequences are properly deemed exclusive. The BPCIA's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U.S. 204, 209 (2002) (citation and internal quotation marks omitted).

C. No Cause Of Action Exists To Compel Disclosure Of Section 262(*l*)(2)(A) Information

The court of appeals' judgment was correct for a second reason: No cause of action exists for independent enforcement of Section 262(*l*)(2)(A).

A plaintiff must possess a private "'cause of action'" in order to "judicially enforce the statutory rights or obligations" it seeks to vindicate. *Davis* v. *Passman*, 442 U.S. 228, 239 (1979); see *Touche Ross & Co.* v. *Redington*, 442 U.S. 560, 568 (1979) ("[T]he fact that a federal statute has been violated and some

person harmed does not automatically give rise to a private cause of action in favor of that person.") (citation omitted). Whether a "cause of action" exists to "enforce the right at issue" is a question "analytically distinct" from both the court's constitutional or statutory jurisdiction to hear the cause and the "question of what relief, if any, a litigant may be entitled to receive." *Davis*, 442 U.S. at 239 & n.18.

This Court has made clear that a "private right[] of action to enforce federal law must be created by Congress." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). "[C]ourts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287. "[A]n implied cause of action" is recognized "only if the underlying statute can be interpreted to disclose [Congress's] intent to create one." *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). And recognizing a cause of action based on inferred, rather than express, intent is a decidedly "rare step." *Paroline* v. *United States*, 134 S. Ct. 1710, 1725 (2014). Even before the Court's more recent decisions significantly narrowed the circumstances under which a private right of action may be inferred, the Court was "extremely reluctant to imply a cause of action * * * that is significantly broader than" an "express civil remedy" that "Congress [has] chose[n] to provide." *Touche Ross & Co.*, 442 U.S. at 574.

The BPCIA, as noted, specifically addresses the consequences of failing to provide Section 262(*l*)(2)(A) information, by making the "*submi*[*ssion*]" of an aBLA an artificial "act of infringement," 35 U.S.C. 271(e)(2)(C)(ii) (emphasis added), actionable under

Section 281's express cause of action for patent-infringement. See pp. 17-18, *supra*. Section 281, however, provides no basis for an action to compel an applicant to supply information under Section 262(*l*)(2)(A) because, as respondents concede, "[f]ailing to provide [such information] is *not* an act of infringement." Cross-Pet. 37. Respondents have never attempted to identify any cause of action permitting a sponsor to seek such an order. That omission is independently fatal to their claim to an injunction based on Section 262(*l*)(2)(A).

D. Respondents' Contrary Arguments Are Misplaced

Respondents' various certiorari-stage arguments reflect a misunderstanding of the BPCIA and relevant governing principles.

1. Respondents argue (Supp. Cert. Br. 11), for instance, that "a declaratory-judgment action is not the same thing as an infringement suit" and that declaratory relief is a "poor 'remedy'" for not providing Section 262(*l*)(2)(A) information. That apparently is so, in respondents' view (Cross-Pet. 34), because a sponsor cannot obtain declaratory relief on a manufacturing-process patent. Congress, however, must be taken to have determined the adequacy of the specific consequences it enacted for failing to provide that information. Moreover, respondents fundamentally misapprehend the statutory scheme.

Section 281 is the only cause of action available on which a sponsor may seek declaratory relief for an (artificial) act of infringement as defined by Section 271(e)(2)(C), and such declaratory relief extends to manufacturing-process patents. See pp. 17-18 & n.5, *supra*. No other provision provides the requisite cause of action. Although Section 262(*l*)(9)(C) cites

the Declaratory Judgment Act, 28 U.S.C. 2201 *et seq.*, that Act "presupposes the existence of a judicially remediable right," *Schilling* v. *Rogers*, 363 U.S. 666, 677 (1960), and merely "enlarge[s] the range of remedies available" with respect to an independent cause of action, *Skelly Oil Co.* v. *Phillips Petroleum Co.*, 339 U.S. 667, 671-672 (1950); *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 288 (1995). See *Ali* v. *Rumsfeld*, 649 F.3d 762, 778 (D.C. Cir. 2011) (Section 2201 does not "provide a cause of action.").

Moreover, declaratory relief is the only form of relief available in artificial-infringement actions at relevant times.[7] Although Section 271(e)(4) authorizes certain monetary and injunctive relief in such actions, 35 U.S.C. 271(e)(4)(B)-(D), a sponsor cannot bring an artificial-infringement action for such relief any significant amount of time before a biosimilar's commercial marketing. Monetary relief is available "only if there has [already] been commercial manufacture, use, offer to sell, or sale * * * or importation" of the biosimilar. § 271(e)(4)(C). A permanent injunction to "prohibit[] any infringement of [a] patent by the biological product" is available in certain circumstances, but only after "the patent is subject to a final court decision" in a Round 1 patent-infringement action,

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[7] The general unavailability of non-declaratory relief is critical to Section 262(*l*)'s patent-dispute-resolution framework. Section 262(*l*)(9) controls the timing and scope of artificial-infringement actions by limiting certain "action[s] under [S]ection 2201 of [T]itle 28 for a declaration of infringement, validity, or enforceability." 42 U.S.C. 262(*l*)(9)(A)-(C). If a sponsor could simply pursue an artificial-infringement action for only *non*-declaratory relief—an action that Section 262(*l*)(9) does not expressly limit—the sponsor could bypass Section 262(*l*)'s detailed patent-dispute-resolution procedures.

§ 271(e)(4)(D), "from which no appeal * * * has been or can be taken," 42 U.S.C. 262(k)(6). That supplemental remedy after a final judgment that grants other relief is not a basis for filing the action in the first instance. Finally, a court may issue an injunction "to prevent the commercial manufacture, use, offer to sell, or sale * * * or importation" of an approved biosimilar, 35 U.S.C. 271(e)(4)(B), but such traditional equitable relief would be available only when such harms are sufficiently real and imminent.[8] Indeed, if a sponsor could establish the imminent commercial launch of a competitor's biosimilar, it would have no need for an *artificial*-infringement claim and could simply bring an action for actual patent infringement under 35 U.S.C. 271(a).[9]

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[8] See *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388, 391-392, 394 (2006) (patent injunction based on actual infringement still requires proof of traditional equitable factors, including that plaintiff "has suffered an irreparable injury"); *City of L.A.* v. *Lyons*, 461 U.S. 95, 111 (1983) ("irreparable injury" warranting permanent injunction requires actual or sufficiently "immediate irreparable injury") (citation omitted); cf. Resp. Supp. Cert. Br. 8 (agreeing that injunction is unwarranted before FDA approval because no "imminent need for judicial action" yet exists).

[9] Courts may grant broader coercive monetary and injunctive relief in actions for *actual* patent infringement. See 35 U.S.C. 283-284. When Congress created artificial-infringement claims for generic drugs under the Hatch-Waxman Amendments in 1984, it clarified that the more limited monetary and injunctive remedies in Section 271(e)(4) were the "only remedies" for artificial infringement, other than an award of "attorney fees under [S]ection 285." 35 U.S.C. 271(e)(4); cf. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678-679 (1990) (describing Section 271(e)(4) as defining "artificial" consequences for "artificial" infringement under an Act that is not an "elegant piece of statutory draftsmanship"). That comparative reference to the normal coercive patent reme-

2. Respondents argue that two purposes are served by continuing Section 262(*l*)'s patent-dispute-resolution process even *after* Section 271(e)(2)(C)(ii) has authorized the sponsor to file an immediate artificial-infringement action on *all* relevant patents. Neither withstands scrutiny.

a. Respondents contend (Cross-Pet. 28) that sponsors would "have no way of knowing" whether any manufacturing-process patents are implicated without the Section 262(*l*)(2)(A) information. That is incorrect. An artificial-infringement claim cannot rest on a manufacturing-process patent alone: Artificial infringement occurs only if the biosimilar itself or one of its uses is claimed in a patent. 35 U.S.C. 271(e)(2); see p. 17, *supra*. And as the Federal Circuit concluded, if a sponsor can file suit on such an artificial-infringement claim, it can obtain discovery into the applicant's manufacturing processes to determine the scope of the artificial infringement. Pet. App. 17a; cf. 35 U.S.C. 295.

b. Respondents also contend (Cross-Pet. 29-30) that if an applicant's failure to provide Section 262(*l*)(2)(A) information ends the Section 262(*l*) process, then Round 1 litigation under Section 262(*l*)(6) will not commence, thereby depriving the sponsor of the final judgment in such litigation that Section 271(e)(4)(D) requires before a sponsor obtains a man-

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dies in Sections 283-285, however, does not also limit declaratory relief for artificial-infringement claims. Such claims were properly understood to give rise to declaratory-judgment actions before Congress enacted the BPCIA, see p. 18, *supra*, and the BPCIA specifically amended the Declaratory Judgment Act to state that 42 U.S.C. 262 ("[S]ection 351 of the Public Health Service Act")—not Section 271(e)(4)—imposes "limitations on actions" for declaratory relief. 28 U.S.C. 2201(b); cf. 42 U.S.C. 262(*l*)(9) (limitations).

datory "permanent injunction prohibiting any infringement of [a] patent by the biological product," 35 U.S.C. 271(e)(4)(D). Assuming *arguendo* that respondents are correct that a court lacks equitable discretion to deny relief under Section 271(e)(4)(D), such a mandatory injunction is logically limited just to Round 1 cases.

The applicant largely controls the scope of Round 1 litigation and can effectively constrain the sponsor's ability to pursue its patent claims in that early lawsuit. See pp. 19-20, *supra*. If a sponsor prevails by obtaining a final and non-appealable judgment in Round 1 litigation notwithstanding the applicant's advantage of control, a mandatory post-judgment injunction serves to counterbalance the limited nature of the proceeding. But where, as here, the sponsor may immediately bring an artificial-infringement action on *all* relevant patents because the applicant has forfeited its control, no such compensation is warranted. The sponsor can pursue all of its patents and, if it prevails, will obtain fully adequate declaratory relief, with the possibility of injunctive relief should actual infringement later become imminent. See p. 18, *supra*.

II. THE FEDERAL CIRCUIT ERRED IN ISSUING AN INJUNCTION TO ENFORCE SECTION 262(*l*)(8)(A)

Section 262(*l*)(8)(A) provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42 U.S.C. 262(*l*)(8)(A). That provision permits an applicant to give the sponsor its 180-day advance notice before FDA approves the aBLA. In any event, no cause of action exists under which respond-

ents could obtain injunctive relief to enforce Section 262(*l*)(8)(A)'s notice requirement.

A. Section 262(*l*)(8)(A) Allows Notice Of First Commercial Marketing Before FDA Approval

1. Notice need only be given "not later" than 180 days "before" commercial marketing

a. The text and purpose of Section 262(*l*)(8)(A)'s notice provision and the BPCIA's broader statutory context show that an applicant may give advance notice of the first commercial marketing of its biosimilar before FDA licenses that biosimilar.

First, Section 262(*l*)(8)(A)'s text directly addresses the question of timing: Notice must be given "*not later than* 180 days *before* the date of the first commercial marketing." 42 U.S.C. 262(*l*)(8)(A) (emphasis added). That language identifies the latest date by which notice must be given, thus allowing an applicant to provide notice *before* that date.

Section 262(*l*)(8)(A) includes no language imposing a front-end restriction limiting how soon the applicant may provide notice after FDA accepts its aBLA. By contrast, when Congress intended in the BPCIA to specify both the earliest and latest dates on which an action could occur, it did so expressly: The very next sentence of Section 262(*l*)(8) specifies that a sponsor may seek a preliminary injunction to enjoin such marketing "[*a*]*fter* receiving the notice * * * *and before* [the] date of the first commercial marketing," 42 U.S.C. 262(*l*)(8)(B) (emphasis added).

Second, requiring notice "not later than 180 days before" commercial marketing reflects the function that Section 262(*l*)(8)(A) plays in Section 262(*l*)'s patent-dispute-resolution framework. If an applicant

follows Section 262(*l*)'s procedures, the BPCIA gives it significant control over the scope of the early Round 1 artificial patent-infringement litigation under Section 262(*l*)(6). The applicant can restrict that litigation to a single patent, see p. 20, *supra*, and neither party may seek a declaratory judgment regarding the remaining (Round 2) patents until "notice is received under [Section 262](8)(A)." 42 U.S.C. 262(*l*)(9)(A).[10]

By requiring the applicant to give notice "not later than 180 days before" the biosimilar's first commercial marketing, 42 U.S.C. 262(*l*)(8)(A), Congress provided a reasonable, 180-day period within which the sponsor may pursue an artificial-infringement action for all remaining patents before the biosimilar's commercial launch. The sponsor also "may seek a preliminary injunction" in that action to halt the biosimilar's impending commercial manufacture or sale "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

But where, as here, the applicant provides more than 180 days notice, the applicant has given the sponsor *more* time than that statutorily required. The permissibility of that earlier notice is consistent with Section 262(*l*)(8)(A) and its surrounding provisions, which facilitate early litigation of patent claims. By contrast, the Federal Circuit disregarded the patent-focused function of Section 262(*l*) by requiring the

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[10] The remaining patents are those "described in clauses (i) and (ii)" of Section 262(*l*)(8)(B), see 42 U.S.C. 262(*l*)(9)(A), that is, the patents that are "included in the [Comprehensive L]ist" under Section 262(*l*)(3), see § 262(*l*)(8)(B)(i), and "*not* included" on the "list of patents" for Round 1 litigation, see § 262(*l*)(8)(B)(ii) (emphasis added).

applicant to give 180-day advance notice *after* FDA approval. Pet. App. 20a. Such notice would delay commercial marketing of a biosimilar for 180 days after approval, even when the sponsor has *no other patents* that arguably should delay such marketing. That strange result has no patent-based justification and would simply delay the statute's otherwise prompt processes for resolving patent disputes between the applicant and sponsor.

b. i. The Federal Circuit inferred its requirement that notice be given after FDA approval from the phrase "the date of the first commercial marketing of the biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A). In the court's view, the word "licensed" indicates that notice "must be given only after the product is licensed." Pet. App. 20a-21a. But "licensed" there is most naturally read as describing the biological product as of "the *date* of [its] first commercial marketing," § 262(*l*)(8)(A) (emphasis added). The statute simply requires that notice be given "not later than 180 days before th[at] date," *ibid.*, a time at which the product may not yet be licensed. The phrase "*the* biological product licensed *under* [*Section 262*](*k*)," *ibid.* (emphasis added), thus serves the function of appropriately identifying the biosimilar whose commercial marketing triggers notice.

The Federal Circuit hypothesized that if Congress had intended Section 262(*l*)(8)(A) "to permit effective notice *before* the product is licensed," it would have used language focused on that situation by referring to the "'product that is the subject of' the application," as it did elsewhere in Section 262(*l*). Pet. App. 20a (emphasis added) (citations omitted). That suggestion ignores that Section 262(*l*)(8)(A)'s 180-day advance

notice can occur either *before* licensing *or* (when commercial marketing begins more than 180 days after FDA approval) *after* licensing. Indeed, Congress used the term "licensed" elsewhere in the BPCIA to describe biosimilars when addressing actions that can occur either before or after FDA approval. Section 262(k)(5)(C)—which concerns regulatory authority that FDA may exercise before "approving the application" or after, 21 U.S.C. 355-1(a)(1) and (2)(A)—specifies that FDA has this same authority for "biological products *licensed* under [Section 262(k)]" as for those "licensed under [Section 262](a)." See 42 U.S.C. 262(a)(2)(D) and (k)(5)(C) (emphasis added).

Moreover, Section 262(*l*)(8)(A)'s specific textual focus on the biosimilar at "the date" upon which its marketing occurs distinguishes it from the other provisions in Section 262(*l*)'s Information and Comprehensive List phases cited by the court of appeals (Pet. App. 20a), that, for instance, require an entity to state its *present* views about the patent-law implications of the future commercial marketing of the "product that is the subject of the subsection (k) application." See, *e.g.*, 42 U.S.C. 262(*l*)(3)(B)(ii)(I) and (C).

ii. The Federal Circuit found its reading preferable because, by requiring that notice be given "after FDA licensure," it ensured that the Round 2 litigation triggered by the notice would involve a "fully crystallized controversy" for "injunctive relief." Pet. App. 21a. That rationale misunderstands, and runs against Congress's policy judgments embodied in, Section 262(*l*).

First, notice allows the sponsor to seek *declaratory* relief on its Round 2 patents by bringing the *artificial* patent-infringement claim in Section 271(e)(2)(C). See 42 U.S.C. 262(*l*)(9)(A); pp. 9, 17-18, 23-24, *supra*. Such

claims for declaratory relief can be fully litigated years before FDA approval. When the parties follow the schedule in Section 262(*l*)(2)-(6), for instance, the same issues for the same patents (if selected for early litigation) can proceed in Round 1 litigation, which would commence no later than roughly 250 days after FDA accepts the aBLA for review. See pp. 5-8, *supra*. And because the aBLA may be submitted eight years before FDA could grant an effective license, § 262(k)(7)(A) and (B), the BPCIA allows such patent litigation more than seven years *before* licensing.

Second, although a sponsor "may seek a preliminary injunction" in a post-notice (Round 2) artificial-infringement action to prevent "commercial manufacture or sale" of the biosimilar, 42 U.S.C. 262(*l*)(8)(B), the BPCIA does not reflect that the sponsor must seek that injunctive relief before commercial manufacture or sale becomes a real and imminent irreparable injury. Preliminary relief is an "extraordinary and drastic remedy" warranted only upon a "clear showing," *Mazurek* v. *Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (emphasis and citation omitted), that the plaintiff "will suffer irreparable injury" without it. *Doran* v. *Salem Inn, Inc.*, 422 U.S. 922, 931 (1975); see also p. 24 & n.8, *supra* (discussing permanent injunction). The Section 262(*l*)(8)(A) notice thus simply allows the sponsor to litigate its artificial-infringement claims on Round 2 patents in an action for declaratory relief and to seek injunctive relief at an appropriate time in that action.

iii. Respondents argue (Br. in Opp. 19) that Section 262(*l*)(9)(A)—which forestalls a declaratory-judgment action for Round 2 patents if the applicant has provided the sponsor with its Section 262(*l*)(2)(A)

information—would be "meaningless" if the notice that lifts that bar could be given as soon as the aBLA is submitted. That is incorrect. Early notice lifts the litigation-focused prohibition in Section 262(*l*)(9)(A) and thus allows either party to file a declaratory-judgment action concerning a Round 2 patent, as it otherwise could have done absent the prohibition.

Respondents also rely on Section 262(k)(6), which addresses an exclusivity period for the first "interchangeable" biosimilar, *i.e.*, a biosimilar that meets additional requirements and may be substituted for its reference product without the prescribing health-care provider's intervention. 42 U.S.C. 262(i)(3). Respondents contend (Br. in Opp. 18-19) that provisions within Section 262(k)(6) "suggest" that commercial marketing should follow FDA approval by "six months," apparently to suggest that this six-month delay supports the similar (but slightly shorter) 180-day post-approval delay that the Federal Circuit imposed. Section 262(k)(6), however, addresses the timing of an FDA interchangeability "determination under [Section 262(k)](4)," § 262(k)(6), which is different from FDA's approval of the product as a biosimilar. As petitioner explains (Br. 36-38), the timing of FDA's approval of a biosimilar application does not necessarily speak to the timing of its separate interchangeability determination.

2. Notice is not required if the applicant declines to provide Section 262(l)(2)(A) information

The Federal Circuit further erred in concluding that an applicant must provide notice under Section 262(*l*)(8)(A) even if the applicant declined at the outset of the BPCIA's patent-dispute-resolution process to disclose its aBLA and manufacturing-process infor-

mation under Section 262(*l*)(2)(A). In the Federal Circuit's view, Section 262(*l*)(8)(A) is a "standalone" notice provision that broadly "allow[s] the [sponsor] a period of time to assess and act upon its patent rights" generally. Pet. App. 25a-26a. That is incorrect.

Notice under Section 262(*l*)(8)(A) serves a more narrowly focused purpose: It terminates the BPCIA's prohibition against an artificial-infringement declaratory-judgment action with respect to *only Round 2 patents*, 42 U.S.C. 262(*l*)(9)(A), and allows the sponsor to seek in that action preliminary injunctive relief pending resolution of its Round 2 patent claims, § 262(*l*)(8)(B). The 180-day advance notice provides a reasonable period to commence Round 2 litigation before commercial marketing. See p. 28, *supra*.

But where, as here, an applicant's failure to take actions specified by Section 262(*l*) allows the sponsor immediately to bring an artificial-infringement action regarding *all* relevant patents, thereby divesting the applicant of its ability to control the pace and scope of litigation, see pp. 17-20, *supra*, the BPCIA's special provisions for litigation of Round 2 patents in Section 262(*l*)(9)(A) and Section 262(*l*)(8)(B) lose their significance. Cf. Pet. App. 43a, 48a-49a (Chen, J., dissenting). In such circumstances, the notice under Section 262(*l*)(8)(A) that triggers those provisions would serve no ongoing statutory function.

B. Injunctive Relief Is Not Available To Compel Notice Under Section 262(*l*)(8)(A)

The Federal Circuit imposed an injunction to enforce its reading of Section 262(*l*)(8)(A)'s notice requirement. Pet. App. 31a. Although respondents state (Br. in Opp. 29-30) that the court had authority under Appellate Rule 8(a) to extend its "injunction

pending appeal," that rationale makes little sense because the court had *resolved* that appeal. The Federal Circuit itself has read its decision here as holding more generally that "an injunction [i]s proper to enforce" Section 262(*l*)(8)(A). *Amgen Inc.*, 827 F.3d at 1054, 1060-1061; see *id.* at 1063-1065. That holding is incorrect for essentially the same reasons that courts may not enjoin an applicant to provide information under Section 262(*l*)(2)(A).

1. First, the BPCIA's detailed provisions specify the exclusive consequences for failing to follow the requirements in Section 262(*l*), all but one of which modify the timing and scope of artificial-infringement litigation. See pp. 5-9, *supra*. Congress made "injunctive relief" available only for a violation of certain confidentiality rules, see 42 U.S.C. 262(*l*)(1)(H), an occurrence that does not halt the ongoing patent-dispute-resolution process. That express provision for non-patent-based injunctive relief reflects an intent to limit such relief to that one Section 262(*l*) context.

The Federal Circuit relied on the purported absence of any provision specifically imposing "consequence[s] for[] noncompliance with [Subsection] (*l*)(8)(A)" where, as here, the applicant also failed to provide the sponsor information at the outset under Subsection (*l*)(2)(A). Pet. App. 24a-25a. If an applicant fails to complete a subsequent step in Section 262(*l*)'s multi-step process after providing such information at the outset—including by failing to provide notice under "[Subsection (*l*)](8)(A)"—the statutory consequence is that the sponsor may bring an artificial-infringement action for all patents on its Comprehensive List. 42 U.S.C. 262(*l*)(9)(B). Although the Federal Circuit correctly noted that that consequence

applies only if the applicant initially provided the information required by Section 262(*l*)(2)(A), Pet. App. 25a, it failed to recognize that specifically identifying such a consequence for failing to give Section 262(*l*)(8)(A) notice is entirely unnecessary if the applicant failed at the outset to furnish the Section 262(*l*)(2)(A) information. In those circumstances, the BPCIA *already* provides that the sponsor may bring suit on any relevant patent following such a failure. 35 U.S.C. 271(e)(2)(C)(ii); see pp. 17-18 & n.5, *supra*.

2. Injunctive relief is also unavailable for an independent reason: No cause of action exists for a sponsor to seek judicial enforcement of Section 262(*l*)(8)(A). See pp. 20-22, *supra*. Respondents simply ignore this shortcoming.

3. Finally, respondents argue (Supp. Cert. Br. 9) that the 180-day-advance-notice provision would be "gutted" if it is not enforceable by injunction. They contend (*ibid.*) that, without an injunction, an applicant could supply the information required by Section 262(*l*)(2)(A) and later launch its biosimilar without notice, thus depriving the sponsor of a fair chance to litigate its Round 2 patents before commercial marketing. Respondent's policy concern cannot overcome Congress's provision of a specific consequence for that scenario, see 42 U.S.C. 262(*l*)(9)(B); does not justify inferring a cause of action to supplement the BPCIA's detailed statutory provisions; and, in any event, is misplaced.

Although 21 C.F.R. 601.51(b) constrains FDA from revealing the existence of an undisclosed aBLA, petitioner correctly explains (Br. 48-51) that a surprise-launch strategy would be infeasible given the amount of public information available by the time FDA ap-

proves a biosimilar. An applicant, moreover, would be quite unlikely to engage in a surprise launch in the face of a potentially viable patent claim, given the applicant's substantial and ongoing monetary investments in its biosimilar (see p. 3, *supra*), which would be put at significant risk by the monetary-damages and injunctive sanctions for actual (not artificial) patent infringement. See Pet. Br. 51. Finally, if an applicant were nevertheless to launch without notice, the district court could take any failure to give notice under Section 262(*l*)(8)(A) into account when exercising its equitable discretion to award preliminary injunctive relief while a sponsor's actual patent-infringement claims are being litigated.

CONCLUSION

The judgment of the court of appeals should be affirmed in part, reversed in part, and remanded.

Respectfully submitted.

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APPENDIX

1. 28 U.S.C. 1338 provides in pertinent part:

Patents, plant variety protection, copyrights, mask works, designs, trademarks, and unfair competition

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. For purposes of this subsection, the term "State" includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.

* * * * *

2. The Declaratory Judgment Act, 28 U.S.C. 2201 *et seq.*, provides:

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the

filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

§ 2202. Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

3. 35 U.S.C. 271 provides in pertinent part:

Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary

biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

* * * * *

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * * * *

(4) For an act of infringement described in paragraph (2)—

* * * * *

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * * * *

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may

not bring an action under this section for infringement of the patent with respect to the biological product.

* * * * *

4. 35 U.S.C. 281 provides:

Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

5. 35 U.S.C. 283 provides:

Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

6. 35 U.S.C. 284 provides:

Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may

increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

7. 35 U.S.C. 285 provides:

Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

8. Section 351 of the Public Health Service Act, 42 U.S.C. 262, provides in pertinent part:

Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

* * * * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

* * * * *

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection

(*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

* * * * *

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to para-

graph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

* * * * *

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

* * * * *

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offer-

ing to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and

legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later

than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforce-

ability of any patent that claims the biological product or a use of the biological product.

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